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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,307	01/16/2002	Hosheng Tu	T&Q-67	2192
7590	03/11/2004		EXAMINER	
Hosheng Tu 15 Riez Newport Coast, CA 92657			KREMER, MATTHEW J	
			ART UNIT	PAPER NUMBER
			3736	3
DATE MAILED: 03/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/050,307	TU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 16 and 18-20 is/are allowed.
- 6) Claim(s) 1-5,7-10 and 12-15 is/are rejected.
- 7) Claim(s) 6,11 and 17 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

### ***Claim Objections***

1. Claims 2-4 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In regard to claims 2-4, these claims do not add any further structural limitation but merely tries to further narrow the "intended use" language "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" of claim 1. In regard to claim 17, the limitation "wherein said given area of tissue is selected from a group consisting of breast tissue, prostate tissue, and brain tissue" does not add any further structural limitation but merely tries to further narrow the "intended use" language "for differentiating in a given area of tissue at tumorous tissue from a normal tissue" of claim 16.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0026127 to Balbierz et al. In regard to claims 1 and 13, Balbierz et al. teaches an apparatus with sensors for measuring impedance and temperature (paragraph 0091 to Balbierz et al.) and a means for effecting tissue temperature by energy source 20 (paragraph 0098 of Balbierz et al.). It is noted that the limitation "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" is merely "intended use" language, which cannot be relied upon to define over Balbierz et al., since Balbierz et al. discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2<sup>nd</sup> 1647. It is further noted that the limitation "comparing said measured tissue impedance over at least a portion of the range of tissue temperatures with reference tissue impedance of the normal tissue adapted for tissue differentiation, wherein said reference tissue impedance is measured over said range of tissue temperatures" was not given any patentable weight since the limitation does not add any structural limitation to the apparatus claim. In regard to claims 2-4, these claims do not add any further structural limitation but merely tries to further narrow the "intended use" language of claim 1. Despite this fact, Balbierz et al. discloses the device is used on breast tissue (paragraph 0118 of Balbierz et al.) as required by claim 2 of the present application and implies that device is used on the prostate (paragraph 0100 of Balbierz et al.) as required by claim 3 of the present application. In regard to claim 12, a drug delivery means is disclosed (paragraph 0095 of Balbierz et al.). In regard to claim 13, non-drug delivery is disclosed. (paragraph

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0088 of Balbierz et al.) In regard to claim 14-15, ultrasound in the range of 300KHz to 3GHz is disclosed. (paragraph 0088 of Balbierz et al.).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0026127 to Balbierz et al. in view of U.S. Patent Application Publication 2001/0001314 to Davison et al. Balbierz et al. teaches that various energy devices can be used to ablate tissue. (paragraphs 0087-0088 of Balbierz et al.). Balbierz et al. does not teach a particular temperature range for ablation. Davison et al. teaches that 40-45 degrees Celsius is a suitable temperature range for ablation. (paragraph 0042 of Davison et al.). This temperature range would fulfill the requirements so that tissue can be ablated. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the temperature range of Davison et al. in the method and apparatus of Balbierz et al. since Balbierz et al. teaches the tissue ablation and Davison et al. teaches a suitable temperature range where ablation can occur. In regard to claim 9, a temperature sensor is disclosed. (paragraph 0098 of Balbierz et al.). In regard to claim 10, a

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combination of RF heating and circulating cooled medium is disclosed. (paragraph 0088 of Balbierz et al.).

6. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0026127 to Balbierz et al. in view of U.S. Patent 6,176,857 to Ashley. Balbierz et al. does not teach that Peltier devices are used. Balbierz et al. teaches that various energy devices can be used to ablate tissue. (paragraphs 0087-0088 of Balbierz et al.). This teaching implies not only that the listed energy devices can be used but any suitable energy devices may be used. Ashley teaches the use of Peltier elements for the treatment of tumors. (column 10, line 48 to column 1, line 6 and column 12, line 64 to column 12, line 6 of Ashley). Such an energy device falls within the scope of providing energy sources as implied by Balbierz et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Peltier element of Ashley in the method and apparatus of Balbierz et al. since Balbierz et al. implies that several different types of energy sources can be used and Ashley et al. teaches one such energy source.

#### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 5, 7, and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/011062 to Tu et al. ('062) in view of U.S. Patent Application Publication 2002/0026127 to Balbierz et al. Claim 12 of '062 discloses a method of differentiating in a given area of tissue of tumorous tissue from a normal tissue by measuring a plurality of tissue impedance with reference tissue impedance of the normal tissue adapted for tissue differentiation (claim 1 of '062 from which claim 12 dependent upon). Claim 12 of '062 does not claim a structure for carrying out the measuring a plurality of tissue impedance. It is well known in the art that electrodes are used for measuring tissue impedance. (paragraph 0091 to Balbierz et al.). Such a structure would provide a way of carrying out the method steps as required by claim 12 of '062. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide electrodes as disclosed by Balbierz et al. in the method of claim 12 of '062 since claim 12 requires a way of measuring tissue impedance and Balbierz et al. teaches on such way. In regard to claim 5 of the present application, the temperature range is identical to the temperature range specified in claim 5 of '062 (from which claim 12 dependent upon). In regard to claims 7-8, claim 12 of '062 claims a means for effecting and monitoring tissue temperatures by claiming a

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structure that is identical to the structure claimed in claims 7-8 of the present application.

This is a provisional obviousness-type double patenting rejection.

***Allowable Subject Matter***

9. Claims 16-20 are allowed.

10. Claims 6 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is an examiner's statement of reasons for allowance. In regard to claim 6, the prior art does not teach or suggest that the range of tissue temperatures is between 20 and 38 degrees Celsius. In regard to claim 16, the prior art does not teach or suggest an apparatus with processing means for analyzing tissue impedance data over the range of tissue temperatures to obtain a first impedance-temperature derivative of the tissue impedance versus tissue temperatures. In regard to claim 20, the prior art does not teach or suggest a method including the method step of acquiring tissue impedance data over the range of tissue temperatures to obtain a first impedance-temperature derivative of the tissue impedance versus tissue temperatures and the step of comparing said first impedance-temperature derivative at a tissue temperature of

interest with reference first impedance-temperature derivative of the normal tissue at said tissue temperature of interest adapted for tissue differentiation.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

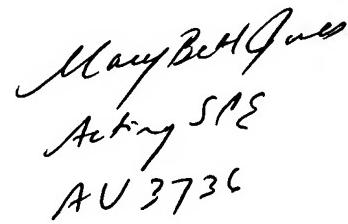
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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